

## § 299.5

name listed in *USAN and the USP Dictionary of Drug Names*. The Food and Drug Administration, however, will continue to publish official names under the provisions of section 508 of the act when the agency determines that:

(1) The USAN or other official or common or usual name is unduly complex or is not useful for any other reason;

(2) Two or more official names have been applied to a single drug, or to two or more drugs that are identical in chemical structure and pharmacological action and that are substantially identical in strength, quality, and purity; or

(3) No USAN or other official or common or usual name has been applied to a medically useful drug. Any official name published under section 508 of the act will be the established name of the drug.

(f) A cumulative list of U.S. adopted names selected and released since June 15, 1961, is published yearly by the U.S. Pharmacopeial Convention, Inc., in *USAN and the USP Dictionary of Drug Names*. Copies may be purchased from

## 21 CFR Ch. I (4–1–05 Edition)

the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

[40 FR 14041, Mar. 27, 1975, as amended at 49 FR 37575, Sept. 25, 1984; 53 FR 5369, Feb. 24, 1988; 55 FR 11577, Mar. 29, 1990; 64 FR 401, Jan. 5, 1999; 69 FR 18803, Apr. 9, 2004]

### § 299.5 Drugs; compendial name.

(a) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium under such recognized name.

(b) The term *drug defined in an official compendium* means a drug having the identity prescribed for a drug in an official compendium.

(c) A statement that a drug defined in an official compendium differs in strength, quality, or purity from the standard of strength, quality, or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference.